UNRAVELING THE MYSTERIES OF CLINICAL TRIALS IN METASTATIC BREAST CANCER

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**WHAT IT MEANS**

<table>
<thead>
<tr>
<th>CLINICAL</th>
<th>TRIAL</th>
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<tr>
<td>Relating to the observation &amp; treatment of actual patients rather than theoretical or laboratory studies</td>
<td>A formal examination of evidence to discover what is true.</td>
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Real patients being treated to answer important research questions.
LAB DISCOVERY TO CLINICAL TRIAL
PHASES OF CLINICAL TRIALS

PHASE I

15-20 participants

Safety
Delivery method
Dosage
Side effects
**PHASES OF CLINICAL TRIALS**

**PHASE I**
- 15-20 participants
- Safety
- Delivery method
- Dosage
- Side effects

**PHASE II**
- 25-100 participants
- Efficacy
- Side effects
**PHASES OF CLINICAL TRIALS**

**PHASE I**
- 15-20 participants
- Safety
- Delivery method
- Dosage
- Side effects

**PHASE II**
- 25-100 participants
- Efficacy
- Side effects

**PHASE III**
- 100s-1000s of participants
- Efficacy compared to available treatments
- Side effects
Treatment is submitted for FDA approval. Once approved, it is available for commercial use.

**PHASE IV**

- 1000s of participants
- Long-term safety
- Long-term efficacy
- Long-term side effects
Drug Discovery & Development-Timeline

- **Drug Discovery**
  - 10,000 Compounds
  - ~6.5 Years

- **Preclinical**
  - 250 Compounds
  - ~7 Years

- **Clinical Trials**
  - 5 Compounds
  - ~1.5 Years

- **FDA Review**
  - 1 FDA Approved Drug
URGENCY IN CLINICAL TRIAL ENROLLMENT

Can take years to enroll required number of patients in a trial

The longer it takes to “accrue” the longer it will take to get results.


• 182 Phase 1 Trials
• 229 Phase 2 Trials
• 44 Phase 3 Trials
US TRIALS FOR MBC: LET’S DO THE NUMBERS

<table>
<thead>
<tr>
<th>Phase</th>
<th>Patients</th>
<th>Estimated Need</th>
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<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>2,184</td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td>11,450</td>
</tr>
<tr>
<td>3</td>
<td>300</td>
<td>13,200</td>
</tr>
</tbody>
</table>

Total Est. Need = 26,834

Est. Number Living in US with MBC Today = 150,000

Need over 17% Participating

Current Participation: Under 10%
GAP IN PARTICIPATION MEANS

- Some trials are terminated
- Takes longer to get a new drug to patients
WHEN TO CONSIDER A CLINICAL TRIAL

Any time you will be starting a new therapy:

- 1st therapy after MBC diagnosis
- Upon progression
- When current therapy limits quality of life

For your Plan B

- Always talk to your oncologist about what happens when your current treatment stops working.
- A trial may have closed at the time of progression or it could still be open.
- Having a trial option and a standard therapy option can provide peace of mind.
FINDING A TRIAL

Your doctor

Your oncology team’s clinical research coordinator

Your own research

Sandi Spivey will share research sources
ELIGIBILITY CRITERIA – MAJOR CATEGORIES

• Your MBC Treatment History:
  • Newly diagnosed MBC – no treatment yet
  • Lightly treated MBC – specific therapies and/or a specific number of lines of therapy
  • Heavily treated – example, 5 or more lines of therapy
  • May require already having or never having a certain therapy

• Location of metastasis
• Receptor Status and/or cancer cell mutations
• Co-Morbidities
• Lab Results
DECIDING ON A TRIAL

You and your doctor talk it over

You do not have to be in a trial within your health provider’s perview

If you can afford the travel, you can opt for a trial anywhere in the world.

Consider number of required visits, travel time and travel expenses when selecting a trial.

Do standard labs/scans have to be done at the clinical trial site?
Are there satellite sites?
An oncology team member contacts the trial coordinator

You consent to release needed medical records

You may need to complete certain eligibility lab tests and scans

Sometimes you need a recent biopsy – tissue or liquid biopsy

Costs for pre-approval medical tests are covered by (?)

Then you wait.....

Requests for additional info/tests may happen
IF NOT APPROVED

You’ll be given a reason why by your oncologist

The researcher team may also provide additional written reasoning

You can appeal

Don’t give up. Look for another trial

You may be able to ask them to suggest another trial that might work for you

Sometimes the Principle Investigator will approve

Don’t give up. Look for another trial
IF APPROVED

- You will still see your regular oncologist for check-ins but not for therapy related issues
- First visit to the CT office: Will be scheduled directly with you or your oncologist’s office. Meet Clinical Trial team member. More…. Set your schedule – treatment, tests, doctor’s visits
- Read, Understand & Signed Informed Consent
INFORMED CONSENT: IMPORTANT

- Purpose of trial
- Length of trial
- Description of your treatment plan
- Voluntary Participation: Describes how to opt out
- What happens if you progress, or if trial ends while still benefitting from test therapy
- Risks/Benefits
- Confidentiality
WHO WORKS ON THE CLINICAL TRIAL TEAM?

- Principle Investigator – usually the trial oncologist you’ll visit
- Study Coordinator
- Clinical Trial Navigator
- Nurse Practitioners / Physician Assistants
- Medical Assistants
- Social Worker
- Others you don't see

You will be scheduled to see the right person at the right time during your treatment.
<table>
<thead>
<tr>
<th>Trial Phase</th>
<th>Triple Negative</th>
<th>ER+/HER2-</th>
<th>ER-/HER2+</th>
<th>Triple Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>UCI 17-76 MBC Pembrolizumab Dr Parajuli: PI</td>
<td>Pipeline</td>
<td>Pipeline</td>
<td>Pipeline</td>
</tr>
<tr>
<td>Phase 2</td>
<td>UCI 14-67 NeoAdjuvant Dr Mehta: PI UCI 18-02 NeoAdjuvant PARP Dr Parajuli: PI UCI 18-79 NeoAdjuvant CDK 4/6 with Fulvestrant Dr Parajuli: PI</td>
<td>UCI 14-67 NeoAdjuvant Dr Mehta: PI UCI 18-06 MBC: Alpelisib Bylieve Trial Dr Parajuli: PI</td>
<td>UCI 14-67 NeoAdjuvant Dr Mehta: PI</td>
<td>UCI 14-67 NeoAdjuvant Dr Mehta: PI</td>
</tr>
<tr>
<td>Phase 3</td>
<td>SWOG S1418 Adjuvant Pembrolizumab Dr Mehta: PI</td>
<td>Alliance (Adjuvant) Dr Mehta: PI TROPICS (Pipeline)MBC Sacituzumab Dr Parajuli: PI UCI 19-22 MBC Abemaciclib Dr Parajuli: PI Phase 4</td>
<td>NRG BR004, MBC Immunotherapy Dr Parajuli: PI</td>
<td>NRG BR004, MBC Immunotherapy Dr Parajuli: PI</td>
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<td>UCI 17-79 MBC Tucatinib with TDM-1 Dr Parajuli: PI</td>
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REMEMBER

• Your participation will make a difference
  • Increases your options
  • May help others living with MBC